



# Empowering Women: A Feminist Argument for Over-the-Counter Sale of Oral Contraceptives

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**Empowering Women: A Feminist Argument for Over-the-Counter Sale of Oral  
Contraceptives**

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**Abstract:** The oral contraceptive pill, having been on the market for 45 years, should be sold over-the-counter. There is no longer any valid reason for FDA to maintain the prescription status of the drug. First, numerous studies over the past few decades have shown that the pill is safe for the vast majority of women, with current risk to users estimated to be less than the risks associated with pregnancy. In addition, the pill is effective and easy to use. Studies have shown that the pill also confers numerous health benefits in addition to its contraceptive indication, including reduction of risk of developing several forms of cancer. When a cost-benefit analysis is undertaken, it is clear that an over-the-counter contraceptive pill provides more benefits than costs to society. Aside from these traditional arguments, it can also be argued that providing women with greater access to the over-the-counter pill will empower women to take control over reproduction to a greater extent than is currently possible, and will thereby decrease the power differential in

male-female sexual relationships. This approach would also end the discriminatory and patronizing practice of conditioning receipt of birth control on annual medical exams. The FDA or other government agencies should implement policies to ensure equal access to the over-the-counter pill and to ensure that the pill remains safe and effective for women.

## **History of the Birth Control Pill**

### A. Medical History

In 1950, the Planned Parenthood Federation of America invited a biologist, Dr. Gregory Pincus, to develop a better contraceptive, described as one which would be “harmless, entirely reliable, simple, practical, universally applicable and aesthetically satisfactory to both husband and wife.”<sup>1</sup> Within a few years, an oral contraceptive was tested clinically in 6,000 women in Puerto Rico and Haiti.<sup>2</sup> By 1960, the first commercially produced birth control pill was released into the U.S. market. It contained synthetic forms of estrogen and progestin, similar to the hormones produced naturally in a woman’s body, which suppress the release of eggs from the ovaries.<sup>3</sup>

American women welcomed the new contraceptive. Within two years, approximately 1.2 million women were using the oral contraceptive, and within five years, this number increased to 5 million.<sup>4</sup> By 1973, about 10 million women were using the pill<sup>5</sup>, and this number has continued to increase, with current use estimated at 11.6 million women in the U.S.<sup>6</sup> However, soon after its introduction, concern grew about the possible side effects of the new contraceptive. As early as 1965, suspicions arose that the pill might predispose some

women to heart attacks and stroke. Some evidence of blood clotting had been reported in women taking the pill.<sup>7</sup> As a result, by 1965, the Food and Drug Administration (FDA) had established its first advisory committee – the Advisory Committee on Obstetrics and Gynecology – to study the possible adverse effects of contraceptives, including the effect of the pill on cancer of the breast, cervix, and endometrium.<sup>8</sup> A year later, the committee concluded that it had found no evidence that the pill was unsafe, but cautioned that long-term studies were necessary.<sup>9</sup> By 1969, researchers had discovered that the risk of blood clots and cardiovascular events was directly related to the amount of estrogen in oral contraceptives, and also that the same rate of contraceptive effectiveness could be maintained with a much lower estrogen dose. By the early 1970s, FDA recommended to doctors that they prescribe the lowest effective dose.<sup>10</sup> This information was included in package labels, and for the first time, FDA required that patient information be included in every package of oral contraceptives.<sup>11</sup> By 1988, at the urging of the FDA, the three drug companies still manufacturing high-dose estrogen pills voluntarily withdrew them from the market.<sup>12</sup> Today's oral contraceptives thus contain much less estrogen and progesterone than early formulations of the birth control pill.

## B. Legal History

Legal rulings on contraceptive use mirrored the increasing popularity of the oral contraceptive. Beginning in 1965, the United States Supreme Court issued a series of rulings overturning state laws banning contraception. In Griswold v. Connecticut, the Court held that a Connecticut law prohibiting the use of contraceptives was unconstitutional because it violated a married couple's right to privacy, which protects their decision to use contraceptives.<sup>13</sup> In 1972, this ruling was extended to include non-married individuals in Eisenstadt v. Baird. In this case, the Court invalidated a Massachusetts law that restricted the distribution or sale of contraceptives to married individuals. The Court found that the right to privacy extends to

individuals who are not married and choose to use contraceptives.<sup>14</sup> Also citing the right to privacy, in 1977 the Court struck down a New York law which banned the sale of non-prescription contraceptives except by licensed pharmacists, the sale or distribution of contraceptives to minors under the age of 16, and contraceptive displays and advertising.<sup>15</sup> Finally, in 1983 the Court upheld a challenge to a federal law that made it a crime to send unsolicited information about contraception via U.S. mail, finding that this interfered with rights of access to information.<sup>16</sup>

### **FDA Regulation of Prescription vs. Over-the-Counter Drugs**

Section 503(b)(1) of the Federal Food, Drug, and Cosmetics Act (hereinafter “the Act”) defines a prescription drug as follows:

A drug intended for use by man which:

(A) is a habit-forming drug to which section 502(d) applies; or

(B) because of its toxicity or other potentiality for harmful effect, or for the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs; or

(C) is limited by an approved application under section 505 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug.

Since oral contraceptives are not one of the habit-forming drugs listed in section 502(d), and also do not fall under category (C) above, their status as a prescription drug falls under category (B). Thus, the current status of oral contraceptives must be analyzed in terms of their potential for toxic or other harmful effects, their method of use, other measures necessary to their use, and their safety without the supervision of a physician.

### **Health and Safety Arguments for Allowing Over-the Counter Sale**

#### A. The Pill is Safe for the Vast Majority of Women

A good argument can be made that the oral contraceptive should no longer be classified as a prescription drug based on toxic or harmful side effects because in fact, today's pill is safe for most women.

The safety profile of oral contraceptives has been demonstrated in millions of women, and taking them is considered safer than the risks attendant to pregnancy.<sup>17</sup> The newer-generation low-dose contraceptives have shown no increased risk of myocardial infarction in healthy non-smoking women,<sup>18</sup> but women with concomitant hypertension, high cholesterol, diabetes, or obesity may have an increased risk of heart attacks.<sup>19</sup> The risk of blood clots increases 2 to 6 times for women taking oral contraceptives, but the overall risk is still low at 1 or 2 persons in 1,000 to 10,000.<sup>20</sup> Most studies indicate that there is no increased risk in women taking oral contraceptives, except in those who smoke.<sup>21</sup> Studies on the link between breast cancer and oral contraceptive use have been inconclusive.<sup>22</sup> There is a slightly increased risk of cervical cancer among women using the pill, but this may be due to an increase in the number of sexual partners among this group<sup>23</sup>. In any

case, all of these increased risks must be weighed against the many benefits provided by oral contraceptives, to be discussed below.

### 1. Comparison to Other OTC Drugs

The safety profile of oral contraceptives is similar to those of drugs that are now sold over-the-counter. For example, long-term use of aspirin can lead to bleeding ulcers, gastrointestinal and urinary tract bleeding, and hemorrhagic stroke (ruptured blood vessels in the brain).<sup>24</sup> These risks are dealt with by simply indicating the possible risks on the label and advising consumers to consult with a physician before using the drug. Likewise, other pain relievers such as NSAIDs have multiple possible side effects, including kidney problems and fluid retention, which can worsen congestive heart failure; liver function abnormalities, headache, dizziness and drowsiness.<sup>25</sup>

### 2. Few Drug Interactions

Those who support maintaining the prescription status of oral contraceptives often point out that certain drugs affect the efficacy of the pill, thereby increasing the risk of unintended pregnancy if there is no physician supervision. However, these risks are clearly listed in the patient package insert for oral contraceptives. Furthermore, the most severe interactions (those that decrease the effectiveness most significantly) are limited to antibiotics and anti-convulsants, both of which require a prescription. Presumably, physicians prescribing these drugs ask patients about medications they are currently taking, and can advise them of the potential

for decreased efficacy and recommend a back-up method of birth control.

Thus, the rationale that birth control pills are unsafe or have toxic or harmful side effects is no longer valid as a reason for maintaining the prescription status of the drug. Oral contraceptives are safe for most women, and any risks to sub-groups of women and drug interactions can be clearly stated on the label, in advertising campaigns, and during physician visits, as they are for many other types of over-the-counter drugs.

### **The Pill is Easy to Use and Effective in Preventing Pregnancy**

Section 503(b)(1) requires prescription status for drugs whose method of use calls for the supervision of a physician. Collateral measures necessary to use of the drug can also suggest the need for prescription status. Neither criterion is met by the oral contraceptive.

A.

#### Ease of Use

Oral contraceptive use involves taking a daily pill. Most formulations come in 28-day or 21-day packages. In the latter case, the woman takes a pill daily for 21 days, then stops taking the pill for 1 week, followed by a new package with 21 pills. In the 28-day formulation, women simply take a pill continuously month-to-month (the last 7 pills in the pack are inactive). Most packages provide women with an adhesive label which designates the day of the week above each pill. In addition, the last 7 pills in 28-day packages are usually a different color from the previous 21 pills. These two features help remind users whether they have missed a



pill and need to take corrective action.

B.

#### Effectiveness

The oral contraceptive is the most effective method of birth control available today, with rates of failure below those of female sterilization. With typical use, which takes into account human errors such as missing a pill, pregnancy rate after one year of use was 5%.<sup>26</sup> But if the pill is taken correctly, the failure rate was 0.1%, compared to 0.5% with female sterilization.<sup>27</sup> Stated differently, the pill is 99% effective in preventing pregnancy if taken properly. In comparison, condoms have a failure rate of 2 percent to 16 percent and the diaphragm has a 6 percent to 18 percent failure rate.<sup>28</sup> While certain antibiotics may reduce the effectiveness of birth control pills, as described above, this fact is already clearly stated on the package label. In addition, since antibiotics require a physician's prescription, it is very likely that the prescribing physician will warn women of the interaction between the drugs.

#### **Oral Contraceptives Confer Numerous Health Benefits**

Oral contraceptives have been shown to reduce the risk of developing several forms of cancer. A study by the Centers for Disease Control found that after 10 to 12 years of oral contraceptive use, the risk of ovarian cancer is reduced by 80 percent and the reduced risk lasts for 15 years.<sup>29</sup> It is believed that the decreased risk results from the inhibition of ovulation.<sup>30</sup> The use of oral contraception has also been linked to a decrease in the risk of developing endometrial cancer. A meta-analysis conducted by the CDC found that oral

contraceptive use has a protective effect, with an approximate 50 percent reduction in the risk for developing the cancer.<sup>31</sup> Oral contraceptives may also be helpful in preventing osteoporosis in post-menopausal women. One study has found that post-menopausal women previously treated with oral contraceptives had higher bone density at menopause than women who had never taken oral contraceptives.<sup>32</sup> Various other studies have shown a decrease in ovarian cysts, benign breast disease, and pelvic inflammatory disease in women taking oral contraceptives.<sup>33</sup> Mead estimates that the reduction in pelvic inflammatory disease would save society \$69.2 million in medical costs alone, and when costs associated with endometrial and ovarian cancer, ovarian cysts, and breast disease are considered, the total savings to society is approximately \$84.5 million per year.<sup>34</sup> Control of the menstrual cycle is another benefit of oral contraceptives. Controlling the timing of their menstrual cycles allows women to manage their lives more effectively,<sup>35</sup> by allowing them to plan ahead for important events such as honeymoons, business meetings, travel, and sporting events. Menstrual cycle timing can also help women with conditions such as premenstrual tension syndrome (PMS), menstrual migraines, and endometriosis.<sup>36</sup>

In addition to these physical health benefits, women would experience significant psychological benefits if they had greater access to the birth control pill. Women who currently use less effective forms of contraception would be reassured that they have a choice of highly effective contraception without the costs of seeing a physician.<sup>37</sup> In addition, this removes the anxiety of having to undergo a pelvic exam, frequently a prerequisite to obtaining a prescription for oral contraceptives. Finally, the reduction in unwanted pregnancies and abortions would significantly decrease the emotional stress associated with these events.<sup>38</sup>

Many health care providers worry that women would no longer see a physician for annual gynecological exams if oral contraceptives were available without a prescription. This could lead to an increase in health

problems that are preventable through annual exams, including sexually transmitted diseases and cervical cancer and therefore lead to an increase in costs to society.<sup>39</sup> However, there is a fundamental problem with the idea that women should be coerced into obtaining annual exams by conditioning receipt of oral contraceptives on this annual exam. After all, physicians do not require invasive prostate exams for men seeking to obtain drugs such as Viagra for sexual dysfunction. It is therefore patronizing and discriminatory to require women to undergo invasive pelvic exams. The health care sector must come up with less coercive ways of encouraging women to obtain regular medical care.

### **Moral, Social, and Political Arguments for Allowing Over-the-Counter Sale**

#### A. Access to Birth Control Empowers Women to Take Control Over Reproduction

It is estimated that 600,000 women worldwide still die each year – and another 18 million are left disabled or chronically ill – due to preventable complications of pregnancy and childbirth.<sup>40</sup> Reproductive freedom is therefore a key component of liberty and autonomy for all individuals, but it has a particularly powerful impact on the well-being of women. Given the complications and stress that a pregnancy can entail for a woman, controlling her number of children has become one of the major measures to ensure her long-term health and quality of life.<sup>41</sup> Modern contraception has allowed women the freedom to “rise above breeding and child-bearing and fight for their rights and equality.”<sup>42</sup> Access to birth control, and reproductive services in general, is also an important element of opportunity and agency for women.<sup>43</sup> Access to family planning, for example, can allow women to balance the size of their family and timing of their children with their need and desire to earn wages.<sup>44</sup> Research has found that use of family planning can improve a woman’s prospects for

wage employment, which can result in both economic and other personal benefits.<sup>45</sup> Family planning can also allow women to seek education or additional training, preparing them for better employment or to take part more fully in a range of other desirable activities.<sup>46</sup> Certainly, contraception can prevent unwanted adolescent pregnancies, thereby facilitating completion of studies and access to better paying work.<sup>47</sup> Research has shown that women who begin childbearing before age 20 complete less schooling than women who delay having children until they are in their 20s.<sup>48</sup> Thus, access to reproductive and sexual health is a pre-condition for women's autonomy. Making choices about the course of her own life asserts woman's fundamental dignity. Lack of control over reproduction and sexuality has dire consequences for women, and severely limits their potential. Without this right, women cannot realize their other rights.<sup>49</sup>

#### B. Access to the Pill Reduces Costs to Women and Society at Large

Over-the-counter sale of birth control pills would allow large numbers of women who do not currently use the drug to take control over reproduction. A survey conducted in 1993 found that 20.4 percent of sexually active women who do not currently use the pill would be very likely to switch to that form of birth control if it were available over-the-counter.<sup>50</sup> Current estimates are that 34 million sexually active women are currently not using oral contraceptives, so a 20.4 percent increase would result in nearly 7 million new users, for an estimated total of 17.4 million women using the pill.<sup>51</sup> This is beneficial because of the number of unintended pregnancies that would be avoided. Based on a 10 percent national rate of unintended pregnancies, approximately 480,000 of the 7 million potential users would become pregnant if they did not use the pill. If the pill were available over the counter, it is estimated that over 467,000 of these pregnancies would be avoided if women used the over-the-counter pill.<sup>52</sup> This leads to reduced costs, both emotional and financial, stemming from avoided abortions, miscarriages, and full term pregnancies. In fact, it is estimated

that the over-the-counter pill would reduce the number of abortions by 220,000 a year.<sup>53</sup> If one takes into account all savings, including abortions, miscarriages, ectopic pregnancies, and the medical costs associated with full-term unwanted pregnancies, the total cost savings to society would be about \$2.08 billion.<sup>54</sup>

Over-the-counter sale of oral contraceptives would also lead to time and cost savings for women who would no longer need to visit a physician to obtain a prescription. Mead estimates that overall, the savings to women who either stop seeing their physician annually or reduce their visits to once a year would equal about \$695.3 million.<sup>55</sup> The time savings in terms of time taken off from work to visit a physician is estimated at \$147 million.<sup>56</sup>

At the same time that over-the-counter sale would decrease costs for women and society, it would increase revenue to pharmaceutical companies, which would in turn likely use this revenue for further research and development initiatives. The higher revenues would come from increased use, because pharmaceutical companies would be unlikely to increase the price of contraceptives.<sup>57</sup> Based on a current average sale price of \$26 a month and an estimated 7 million new users, companies would see an increase in revenue of over \$2 billion.<sup>58</sup> There has been some concern expressed about whether low-income women and those without health insurance would be disadvantaged by the over-the-counter sale of birth control pills. Also, women whose health insurance plans currently pay for prescription oral contraceptives may deny coverage if the pill is sold over-the-counter. It is interesting to note that since costs of the drug would increase little or nothing at all, women who currently purchase the pill through health insurance would see just a slight increase in monthly costs, and those who receive the drug through publicly-funded women's health centers would presumably continue to receive the drug free of charge, although pharmaceutical companies may be more reluctant to offer the drugs to clinics at discounted prices.<sup>59</sup> However, if these issues become problematic, the FDA or

other government agencies can take steps to minimize increases costs for women, as discussed below.

#### D. Access to Birth Control Decreases the Power Differential in Male-Female Relationships

Another aspect of how access to birth control increases female autonomy has to do with the power differential between men and women in most, if not all, societies. Worldwide, greater investment in reproductive health services, including greater access to birth control, has led to significant reductions in infant and maternal mortality and declines in fertility rates, reducing women's burdens associated with childbirth and child rearing.<sup>60</sup> In some countries, women's life expectancy has increased by up to a decade over that of just 30 years ago. These improvements mark important progress in women's well-being and their capacity to participate fully in society.<sup>61</sup>

Increased access to birth control has also contributed to reducing inequalities between women and men. A recent analysis conducted by the World Bank (2001) establishes that women bear the largest and most direct cost of gender inequality and lack of empowerment. These costs are individual, societal, and inter-generational. For example, women's economic dependency on men reduces their ability to leverage safer sex options to protect themselves against unwanted pregnancies and HIV infection<sup>62</sup>. Because men are in control of condom use, women in powerless situations cannot effectively control reproduction and exposure to sexually transmitted diseases. Gender inequality often leads to violence, and violence against women, which is a gross infringement of women's rights, has severe health and economic consequences for women.<sup>63</sup> Over-the-counter sale of oral contraceptives would put the power to control reproduction in women's hands, without having to rely on their male partners' choice or non-choice to use birth control methods such as condoms.

#### D. Requiring a Prescription for Oral Contraceptives is Patronizing towards Women

Apart from the broader societal policy reasons mentioned above, requiring a prescription for oral contraceptives is patronizing towards women. One reason advanced for maintaining oral contraceptives as a prescription drug include the incentive it provides for annual exams and the possible confusion it would cause if women had to choose a formulation on their own. As stated above, many health professionals use their power over prescribing contraceptives to women to force them to undergo annual pelvic exams and gynecological care. This argument is not without merit. Lack of medical care and preventative screening would likely lead to increases in cervical and breast cancer and undiagnosed sexually transmitted diseases and pelvic inflammatory disease. Assuming that these risks would double if women chose not to undergo annual exams, Mead estimates that the total cost to society associated with this increase would equal \$407 million.<sup>64</sup> However, as stated above, it is irrational to require women to undergo annual exams while at the same time not requiring men to undergo invasive prostate and testicular cancer exams before dispensing Viagra or other erectile dysfunction drugs. In addition, women would likely visit a physician at least once a year for other reasons, and doctors can advise them at that time of the importance of gynecological exams. But women should not be forced to choose between controlling the number of children they bear and undergoing invasive procedures that they do not want.

A related concern expressed by those opposing over-the-counter sale is that women will be confused about how to use oral contraceptives if there is no physician to guide them. First, this assumes that women are not able to call or visit a physician or other health care provider to obtain guidance on how to use the pill. Many simple questions can be resolved with a brief phone call to a family physician. In addition, oral contraceptives already include detailed patient instructions on use, which are easy to read and understand. Manufacturers

would likely put several different formulations on the market, including mono-phasic, bi-phasic, and tri-phasic pills of different doses. While it is true that women may become confused about which products best suits their needs, this is again remedied by a simple call to a physician or a brief consultation with the pharmacist. It is likely that most manufacturers would extensively advertise their products once they were available over-the-counter, and this combined with detailed labeling and guidance from health professionals should be more than enough to provide women with the information they need to make a careful choice among products. Finally, some health professionals have expressed concern that women may rely on the pill to prevent sexually transmitted diseases, including HIV. While this argument may hold some weight in the case of teenagers or extremely uneducated adult women, most women are aware of the pill's mechanism of action, and detailed labeling and guidance from physicians would easily remedy this problem. Perhaps the F.D.A. can even impose a requirement that women sign a release at the pharmacy stating that they understand that the pill does not protect against sexually transmitted disease.

This last proposal leads to another suggestion for over-the-counter sale; a sort of mid-point between prescription and non-prescription status. If the F.D.A. decides that switching oral contraceptives to non-prescription status is too risky at this time, perhaps the drug can be sold without a prescription, but "behind-the-counter." Behind-the-counter sale already is in place at some pharmacies across the country for such items as home HIV tests and glucose tests. Women would have to ask the pharmacist for the oral contraceptive, and the pharmacist would then be required to provide basic information to the purchaser, including the fact that the pill does not prevent HIV, that smokers and those with other diseases should not take the pill, and offer to answer any questions the woman may have about the pill. In this way, women are given the freedom to choose oral contraceptives without the costs of seeing a physician, while at the same time ensuring that they are provided with sufficient information for correct use.



## **Recommendations for Implementing Over-the-Counter Sale**

After conducting a cost-benefit analysis, Mead recommends that the FDA approve over-the-counter sale of the birth control pill. Her analysis shows that public health benefits associated with reduced rates of unplanned pregnancies and abortions and the medical cost savings to society substantially outweigh any risks of increased and unsupervised use of oral contraceptives, and the net benefit to society would equal \$2.06 billion.<sup>65</sup> To prevent possible problems associated with over-the-counter sale, Mead suggests that FDA adopt several policies. First, FDA should require that manufacturers of oral contraceptives provide an extensive education campaign emphasizing the importance of annual pelvic exams.<sup>66</sup> This campaign could be waged on both television and in print, and it should also identify the groups of women who should not use oral contraceptives.<sup>67</sup> To address the issues surrounding increased out-of-pocket costs for consumers, the government should mandate that Medicaid and private insurance companies cover the costs of over-the-counter oral contraceptives.<sup>68</sup> Likewise, pharmaceutical companies should be encouraged to continue providing discounted prices to publicly-funded health clinics.<sup>69</sup> Together, these measures would eliminate any added costs that the switch would create for lower-income women and would ensure that all women wishing to use oral contraceptives are given the opportunity to do so without the added costs and burdens currently imposed by the drug's prescription status.

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